

Appl. No. 09/402,446
Amdt. Dated September 2, 2003
Reply to Office action of April 22, 2003

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-22 (deleted).

Claim 23 (currently amended): A method of increasing the serum half-life of an immune globulin comprising:

(a) combining the immune globulin and ~~at least one~~ a non-ionic surface active agent into an immune globulin preparation wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said ~~one or more~~ non-ionic surface active agent(s) is in a concentration sufficient to increase the serum half-life of the immune globulin; and

(b) parenterally administering the immune globulin preparation to an animal in need of the immune globulin.

Claim 24 (previously amended): A method according to claim 23 wherein the immune globulin is anti-D immune globulin.

Claim 25 (previously amended): A method according to claim 24 wherein the anti-D immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 26 (previously amended): A method according to claim 25 wherein the immune globulin preparation is an aqueous formulation.

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Claim 27 (previously added): A method according to claim 23 wherein the immune globulin is anti-c immune globulin.

Claim 28 (previously added): A method according to claim 27 wherein the anti-c immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 29 (previously amended): A method according to claim 28 wherein the immune globulin preparation is an aqueous formulation.

Claim 30 (deleted).

Claim 31 (currently amended): A method according to claim 23 wherein the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ a sorbitan ester of a fatty acid.

Claim 32 (currently amended) A method according to claim 31 wherein the non-ionic surface active agent(s) ~~is(are)~~ selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 33 (currently amended) A method according to claim 23 wherein the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ a polyoxyethylene sorbitan ester of a fatty acid.

Claim 34 (currently amended) A method according to claim 33 wherein the non-ionic surface active agent(s) ~~is(are)~~ selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

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Claim 35 (currently amended): A method according to claim 23 wherein ~~two or more~~ the non-ionic surface active agents are is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate; polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate; sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 36 (currently amended) A method according to claim 23 wherein the concentration of the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ about 0.01 weight percent to about 0.5 weight percent.

Claim 37 (previously added): A method according to claim 23 wherein the immune globulin preparation is a lyophilized preparation.

Claim 38 (previously amended) A method according to claim 23 wherein the immune globulin preparation comprises:

about 3-8% human anti-D immune globulin with an IgG purity of greater than 95% and a monomeric protein content of greater than 94%;

sodium chloride at about 0.25% (w/v);

polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and

L-glycine at about 0.1M.

Claim 39 (currently amended) A method according to claim 23 wherein the ~~one or more~~ non-ionic surface agents are is selected from the group consisting of glyceryl monooleate; and a polyvinyl alcohol.

Claims 40-56 (deleted).

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Claim 57 (currently amended): A method of increasing the serum half-life of a polyclonal immune globulin comprising:

(a) combining the polyclonal immune globulin and ~~at least one~~ a non-ionic surface active agent into an immune globulin preparation, wherein said ~~one or more~~ non-ionic surface active agent~~s~~ is in a concentration sufficient to increase the serum half-life of the polyclonal immune globulin; and

(b) parenterally administering the immune globulin preparation to an animal in need of the immune globulin.

Claim 58 (previously added): A method according to claim 57 wherein the immune globulin is anti-D immune globulin.

Claim 59 (previously added): A method according to claim 58 wherein the anti-D immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 60 (previously added): A method according to claim 59 wherein the immune globulin preparation is an aqueous formulation.

Claim 61 (previously added): A method according to claim 57 wherein the immune globulin is anti-c immune globulin.

Claim 62 (previously added): A method according to claim 61 wherein the anti-c immune globulin has an IgG purity of greater than about 95% and a monomeric protein content of greater than about 94%.

Claim 63 (previously added): A method according to claim 62 wherein the immune globulin preparation is an aqueous formulation.

Claim 64 (previously added): A method according to claim 57 wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent.

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Claim 65 (currently amended): A method according to claim 57 wherein the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ a sorbitan ester of a fatty acid.

Claim 66 (currently amended) A method according to claim 65 wherein the non-ionic surface active agent(s) ~~is(are)~~ selected from the group consisting of sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

Claim 67 (currently amended): A method according to claim 65 wherein the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ a polyoxyethylene sorbitan ester of a fatty acid.

Claim 68 (currently amended): A method according to claim 67 wherein the non-ionic surface active agent(s) ~~is(are)~~ selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate, polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate.

Claim 69 (currently amended): A method according to claim 57 wherein ~~two or more~~ the non-ionic surface active agents ~~are~~ is selected from the group consisting of polyoxyethylene (20) sorbitan monolaurate, polyoxyethylene (4) sorbitan monolaurate, polyoxyethylene (20) sorbitan monopalmitate; polyoxyethylene (20) sorbitan monostearate, polyoxyethylene (4) sorbitan monostearate, polyoxyethylene (20) sorbitan tristearate, polyoxyethylene (20) sorbitan monooleate, polyoxyethylene (5) sorbitan monooleate, and polyoxyethylene (20) sorbitan trioleate, sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, and sorbitan trioleate.

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Claim 70 (currently amended): A method according to claim 57 wherein the concentration of the ~~one or more~~ non-ionic surface active agent(s) ~~is(are)~~ about 0.01 weight percent to about 0.5 weight percent.

Claim 71 (previously added): A method according to claim 57 wherein the immune globulin preparation is a lyophilized preparation.

Claim 72 (previously added): A method according to claim 57 wherein the immune globulin preparation comprises:

about 3-8% human anti-Dimmune globulin with an IgG purity of greater than 95% and a monomeric protein content of greater than 94%;
sodium chloride at about 0.25% (w/v);
polyoxyethylene sorbitan monooleate at about 0.01% to about 0.5% (w/v); and
L-glycine at about 0.1M.

Claim 73 (currently amended): A method according to claim 57 wherein the ~~one or more~~ non-ionic surface agents ~~are~~ is selected from the group consisting of glyceryl monooleate; and a polyvinyl alcohol.